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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,581	01/15/2004	Matthias Gerlach	247649US0DIV	4522

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EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,581	Applicant(s) GERLACH ET AL.	
	Examiner Robert Shiao	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 12/23/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 147-273 is/are pending in the application.
- 4a) Of the above claim(s) 191-200, 208-220, 246-263 and 268-273 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 147-190, 201-207, 221-245 and 264-267 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/149,449.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
GERMANY 199 63 179.4 with a filing date 12/27/1999.
2. Claims 147-273 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statements, filed on January 15, 2004, have been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of Group I claims 147-190, 201-207, 221-245 and 264-267, in part, in the reply filed on December 23, 2005, is acknowledged. An elected species, i.e., 4-chloro-2-(mopholin-4-yl-o-tolylmethyl)-naphthalinl-ol of example 18, is also acknowledged. The traversal is on the grounds that (1) the Office fails to consider that there is indeed a common significant structural element that is shared by all: preparation of medicament for treating diseases; and (2) the Office has not even established a prima facie search burden, M.P.E.P 1893.03(d) and M.P.E.P. 803 are cited. This is not found persuasive and reasons are given, *infra*.

It is noted that the instant restriction requirement is under 35 U.S.C. 121, when claims involve more than one independent or distinct invention, i.e., Compounds, Methods of Use, Methods of Making, etc., the claims may be restricted and the examination limited to a restricted invention. However, even though an art rejection has

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not been made in this application, the requirement for restriction is maintained and the search has not been extended. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. In the instant case, Groups III-IV of processes of making, Groups V-IX of methods of use, and Groups X-XI of another product, involve more than one independent or indistinct invention.

Claims 1-35 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 147-190, 201-207, 221-245 and 264-267, in part, drawn to compounds/compositions of formula (I), wherein the heteroaryl of variable R^3 - R^8 represents thiophenyl, pyrrolyl or furfuryl thereof; the variable R^9 or R^{12} independently does not represent heteroaryl thereof; and when R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine thereof. The elected species read on the elected subject matter.

The above mentioned withdrawn compounds, processes of making (i.e., Group III-IV), methods of use (i.e., Groups V-IX) or other products (i.e., Group X-XI) which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds/compositions, processes of making, or methods of use contain varying heterocycle or heteroaryl of the variables R^3 - R^9 of the formula (I) having pyridyl, or

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piperazine moiety, which differ from those of the elected invention having morpholine moiety, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classifications of these functional groups in the U.S. classification system, i.e., class 546 subclass 249(+) (pyridyl), class 544 subclass (336+) (piperazine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in common structure and composition and have been restricted properly.

The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 147-190, 201-207, 221-245 and 264-267, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 147-190, 201-207, 221-245 and 264-267, in part, not embraced in above elected subject matter, and claims 191-200, 208-220, 246-263, and 268-273 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 147-190, 201-207, 221-245 and 264-267 are rejected under 35

U.S.C. 102(a) as being anticipated by (1) Katritzky et al. publication, Journal of Organic Chemistry, 1999, 64(16), 6071-6075, also see CAS:131:243022. Claims 147-190, 201-207, 221-245 and 264-267 are rejected under 35 U.S.C. 102(b) as being anticipated by (2) Saidi et al. publication, Journal of Chemical Research, Synopses, 1997, (9), 340-341, also see CAS:128:13099; (3) Komissarov et al. publication, Izvestiya Akademii Nauk, Seriya Khimicheskaya, 1992, 10: 2389-99, also see CAS :118 :254274; (4) Fateen et al. publication, Egyptian Journal of Chemistry, 1972, 15(4), 329-36, see CAS: 80:108438; (5) Seshadri et al. publication, Indian Journal of Chemistry, 1969, 7(11), 1080-3, also see CAS: 72:31500; (6) Bell et al. publication, Journal of Organic Chemistry, 1958, 23, 789-93, see CAS: 53:7062; or (7) Hassner et al. publication, Journal of the American Chemical Society, 1957, 79, 230-4, also see CAS: 51:34766.

Applicants claim a compound of formula (I), see claim 147. Dependent claims 148-190, 201-207, 221-245 and 264-267, drawn to compounds/compositions of formula (I), having limitation of variables R^3 - R^9 , i.e., at least one of the radicals R^3 - R^8 represents hydrogen. The compound is found on the pages 2-67 of the specification.

Katritzky et al. disclose two compounds, i.e., 2-Naphthalenol, 1-(4-morpholinylphenylmethyl)-, and 2-Naphthalenol, 1-[4-morpholinyl(4-nitrophenyl)methyl]-, see page 6073, lines 40-42, compound No. (6a), or page 6074, lines 49-50, compound No (6i), or see RN: 24685-08-3 or 244184-48-3 of CAS: 131:243022. Katritzky et al. compounds clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., phenyl or nitrophenyl), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine; the variable R^2 represents OR^{12} , and R^{12} represent H; the variables R^3 - R^8 represents H.

Saidi et al. disclose three compounds, i.e., 2-Naphthalenol, 1-[1-(4-morpholinyl)-3-phenylpropyl]-, 2-Naphthalenol, 1-[1-(4-morpholinyl)ethyl]-, or 1-Naphthalene-propanoic acid, .beta.-(diethylamino)-2-hydroxy-, ethyl ester, or compounds No. 8a, 8b, 8c, or 8e on page 341, or see RN: 198987-08-5, 198987-10-9 or 198986-99-1 of CAS: 128:13099. Saidi et al. compounds clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., phenylethyl) or alkyl radical (i.e., methyl, $-CH_2-(C=O)-OEt$, CH_2CHCH_2), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine, or R^{10} and R^{11} independently represent C_{1-6} alkyl (i.e., ethyl, ethyl); the variable R^2 represents OR^{12} , and R^{12} represent H; the variables R^3 - R^8 represents H.

Komissarov et al. disclose two compounds, i.e., 2-Naphthalenol, 1-[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-4-morpholinylmethyl]-6-bromo-, and 2-Naphthalenol, 1-[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-4-morpholinylmethyl]-, see RN: 147711-20-4 or 147711-19-1. Komissarov et al. compounds clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., 3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl) or alkyl radical (i.e., methyl), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine; the variable R^2 represents OR^{12} , and R^{12} represent H; the variables R^3 - R^8 represents hydrogen or the variable R^6 represents Br and R^3 - R^5 , and R^7 - R^8 represents H.

Fateen et al. disclose three compounds, i.e., 1-Naphthalenol, 2-[(4-methoxyphenyl)-4-morpholinylmethyl]-7-methyl-, 1-Naphthalenol, 2-[(4-methoxyphenyl)-4-morpholinylmethyl]-5,7-dimethyl-, or 1-Naphthalenol, 7-methyl-2-(4-morpholinylphenylmethyl)-, see compounds No. aj, fj, or ij on page 334, or see RN: 52159-83-8, 52159-86-1, or 52159-87-2 of CAS: 80:108438. Fateen et al. compounds clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., methoxyphenyl or phenyl), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a

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morpholine; the variable R^2 represents OR^{12} , and R^{12} represent H; the variable R^4 or R^6 independently represents H or C_{1-10} alkyl (i.e., methyl), and R^3 , R^5 , R^7 - R^8 represents H.

Seshadri et al. disclose three compounds, i.e., 2-Naphthol, 1-[p-(dimethylamino)-.alpha.-morpholinobenzyl]-, 2-Naphthol, 1-(p-methoxy-.alpha.-morpholinobenzyl)-, or 2-Naphthol, 1-(.alpha.-morpholinoveratryl)-, see compounds No. II-IV on page 1080, or see RN: 24685-05-0, 24685-06-1, or 24685-07-2 of DN: 72:31500. Seshadri et al. compounds clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., methoxyphenyl or dimethylaminophenyl), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine; the variable R^2 represents OR^{12} , and R^{12} represent H; the variable R^4 or R^6 independently represents H or C_{1-10} alkyl (i.e., methyl), and the variables R^3 - R^8 represents H.

Bell et al. disclose one compounds, i.e., 1-Naphthalenol, 2-[4-morpholinyl(2-nitrophenyl)methyl]-, see RN: 6628-55-3. Bell et al. compound clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., nitrophenyl), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine; the variable R^2 represents OR^{12} , and R^{12} represent H; the variables R^3 - R^8 represents H.

Hassner et al. disclose two compounds, i.e., 1-Naphthol, 2-alpha-morpholinobenzyl-, hydrochloride, or 1-Naphthol, 2-alpha-morpholinobenzyl-, see RN: 102474-88-4 or 102474-89-5. Hassner et al. compounds clearly anticipate instant compounds of formula (I) of claim 147, wherein the variable R^1 represents $CH(R^9)N(R^{10})(R^{11})$, the variable R^9 represents an aryl radical (i.e., phenyl), R^{10} and R^{11} together denote $(CH_2)_2O(CH_2)_2$, and said $(CH_2)_2O(CH_2)_2$ with the adjacent nitrogen (i.e., from $CH(R^9)N(R^{10})(R^{11})$) form a morpholine; the variable R^2 represents OR^{12} , and R^{12} represent H; the variables R^3 - R^8 represents H. Hassner et al. compound, i.e., 1-Naphthol, 2-alpha-morpholinobenzyl-, reads on the last compound of claim 190.

Dependent claims 148-190, 201-207, 221-245 and 264-267 of claim 147, drawn to compounds/compositions of formula (I), are rejected along with claim 147 under 35 U.S.C. 102(a) or (b).

Claim Objections

6. Claims 147-190, 201-207, 221-245 and 264-267 are objected to as containing non-elected subject matter, i.e., heteroaryl of the variable R^9 or R^{12} , etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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